REMARKS/ARGUMENTS

Applicants acknowledge with appreciation the withdrawal of rejections of claims 2, 10 and 12 under 35 U.S.C. § 112, ¶2, claims 20-35 and 42 under 35 U.S.C. § 112, ¶1, and the enablement rejections regarding the type of radiation used, and the product claims. Based upon the Advisory Action, it is Applicants' understanding that the following issues remain: claim 19 stands rejected under 35 U.S.C. § 112, ¶1, for lack of enablement; and claims 1, 2, 5-16 and 18-44 stand rejected under 35 U.S.C. § 103 as obvious in light of three prior art publications. Further, even though there is no formal rejection, the Examiner has pointed out that claims 4, 19 and 43 are indefinite on the grounds of improper dependency, and lack of antecedent basis.

Claim 4 has been amended to depend from claim 1, and to recite the chemical agents in Markush form. Claim 19 has been amended to delete the recitation "protoplasts". Claim 43 has been amended to recite that chromosome fragments are produced via irradiation. These amendments have been made simply to address antecedent basis and dependency issues. No new matter is included in these amendments. Entry of these amendments is respectfully requested.

35 U.S.C. § 112, ¶1

The Examiner has rejected claim 19 as lacking enablement on the ground that the specification does not enable one skilled in the art to produce chromosome fragments in whole plants by irradiating whole plants. The Examiner has also pointed out that step (b) references the "protoplasts of (a)", but step (a) does not recite protoplasts. As indicated above, step (b) of claim 19 has been amended to delete the recitation "protoplasts", and thus clarify that whole plants are irradiated. In addition, Applicants submit that the

specification does enable production of chromosome fragments in whole plants via irradiation. Specifically, page 9, lines 11-21, teach each step in this process, namely, producing transformed plants, treating "whole transgenic plants or pollen from whole transgenic plant[s]. . . with an agent, such as irradiation, to induce chromosome fragmentation", crossing the irradiated plant with a normal plant, and identifying the hybrid progeny. This disclosure must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein. (*In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971)) (emphasis in original). It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. (*Marzocchi*, 439 F.2d at 224).

Respectfully, these standards have not been met. Rather, the Examiner has merely questioned whether the transformed plant could be "crossed" once it has been irradiated. In other words, he expresses doubt that the claimed invention actually works. In any event, the specification teaches that progeny from crosses between irradiated and non-irradiated plants can be made. "It has been shown (Pandey, *Nature 256*:310-313 (1975)) that crosses between irradiated and normal plants can be done and result in transfer of marker traits from the irradiated organism." (Specification p. 9, lines 16-19). Therefore, Applicants submit that claim 19 is enabled.

In light of the foregoing, Applicants respectfully request withdrawal of this rejection.

In addition, while the Examiner has not issued any formal rejections, the last paragraph of the Advisory Action indicates that claims 4, 19 and 43 are indefinite. Applicants submit that these rejections are rendered moot in light of the amendments to those claims.

35 U.S.C. § 103(a)

Claims 1, 2, 5-16, and 18-44 stand rejected as obvious over *Famelaer et al.*, (*Theor. Appl. Genet.*, Vol. *79*: 513-520 (1990), in view of *Blume et al.*, (*Plant J.*, *12*:731-746 (1997), and *Adam et al.*, (*Plant J.*, *11*:1349-1358 (1997). Essentially, the Examiner's position remains that the method taught in *Famelaer* differs from the presently claimed invention only in that *Famelaer* does not teach transgenic nucleic acid in the chromosomes of the protoplasts to be irradiated. Applicants respectfully disagree.

Famelaer teaches fusion of irradiated protoplasts and non-irradiated protoplasts to create parasexual hybrid plants, which in some cases contained a random number of various chromosomes from a donor plant. (*Famelaer* at 513). First, *Famelaer* does not teach transformation of protoplasts with exogenous nucleic acid prior to irradiation to produce chromosome fragments. Second, *Famelaer* does not teach the selection of chromosome fragments (referred to in the present specification as artificial minichromosomes) containing the exogenous nucleic acid, and that exhibit normal plant chromosomal activities.

The Examiner has determined that it would have been obvious to one of ordinary skill in the art to modify *Famelaer's* method by producing protoplasts from transgenic plants as taught by *Blume* and YAC vectors as taught by *Adam*. However, *Blume* and *Adam* merely disclose various vectors and their use in plant transformation. More specifically, *Blume* teaches expression of

the GUS selectable marker operably linked to an ACC oxidase promoter by insertion of the GUS coding region into restriction enzyme sites in a plant transformation vector prior to introduction into a plant. (*Blume* at 732-738). *Adam* teaches the use of YAC vectors that can be used to stably transform plant cells. (*Adam* at 1350-1353).

Applicants submit that it would not have been obvious to one skilled in this art to produce the claimed invention in view of the collective teachings of *Famelaer, Blume* or *Adam*. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (*Carella v. Starlight Archery*, 804 F.2d 135, 140, 231 U.S.P.Q. 644, 649 (Fed. Cir. 1986). As annunciated by the Federal Circuit in *In re Vaeck*, proper analysis of obviousness requires consideration of two factors:

> (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

(947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991)). Neither factor is met in this case. The collective publications would not have suggested one skilled in the art to modify *Famelaer's* method by (1) transforming protoplasts with exogenous nucleic acid prior to irradiation and then (2) selecting minichromosomes (chromosome fragments) containing exogenous nucleic acid, and that exhibit normal plant chromosomal activity. *Blume* and *Adam* disclose various vectors and their use in plant transformation, which may be useful in a variety of plant transformation techniques. Neither reference teaches nor suggests employing them in conjunction with *Famelaer's* method,

specifically by using them to transform *Famelaer's* protoplasts prior to irradiation.

Even if such a suggestion were present, one of ordinary skill in this art would not have had a reasonable expectation of success in producing the claimed invention. *Famelaer* created parasexual hybrid plants that in some cases, but not all, contained random number of chromosomes from the donor plant. (*Famelaer* at 513). *Famelaer* observed that the plants did not exhibit normal plant chromosomal activities. Of *Famelaer*'s R_1 generation, only two plants were "almost normally self-fertile"; "reduced fertility was observed" for progeny plants; and decreased transmission rate was observed with increasing fertility. (*Famelaer* at 515, 516) (emphasis added). Thus, *Famelaer*, by his own admission, was unable to control or achieve consistent results with respect to chromosome transmission or normal chromosomal activity. Simply put, the results were unpredictable. On the basis of these results, one skilled in the art would not have had a reasonable expectation of success that a modification of *Famelaer's* method, that entailed transformation of the protoplast with exogenous nucleic acid prior to irradiation and then fusing, would result in fused protoplasts or cells derived therefrom, that contain chromosome fragments containing the exogenous nucleic acid and that exhibit normal plant chromosomal activities. Absent such motivation or reasonable expectation of success, the only way in which such a conclusion can be made is by the improper application of hindsight reconstruction.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass

this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefore.

Dated: March 7, 2006

Respectfully submitted,

By Shawn P. Foley

Shawn P. Foley
Registration No.: 33,071
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

628154_1.DOC